



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,741	05/01/2001	Samuel T. Henderson	ACC.01	3451

25871 7590 02/02/2005
SWANSON & BRATSCUN L.L.C.
1745 SHEA CENTER DRIVE
SUITE 330
HIGHLANDS RANCH, CO 80129

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,741	Applicant(s) HENDERSON, SAMUEL T.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 12, 2004 has been entered.

Claim 11 is now pending. The prior art rejection over Blackburn is withdrawn because the cited art does not teach element (a) of the instant claims.

Applicant's arguments have been considered but are moot in view of new grounds rejection and reasoning.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "Alzheimer's type" is relative in nature. The specification does not clearly ascertain the scope of such limitation. Accordingly, it the metes and bound of the claim is viewed indefinite.

In view of Applicant's arguments submitted on November 12, 2004, the metes and bounds of the term phrase "medium chain triglyceride prodrug" appears ambiguous.

As the initial matter, the specification does not clearly define the metes and bound of this term. Subsequently, for the purposes of Examination, as Applicant may act as own lexicographer in a patent application, Examiner viewed this phrase to be directed to medium chain triglycerides (MCT) that act as prodrugs for medium chain fatty acids (MCFA) once in vivo. In fact, the Specification supports this interpretation, because it refers MCT to be metabolized to MCFA (see specification at pages 9-10).

However, in his November 12, 2004 filing, Applicant appears to argue that the phrase "medium chain triglyceride prodrugs" are directed to moieties that act as precursors or prodrugs to MCT. (see Applicant's arguments at page 4, 2nd para. stating that even though Schmidl teach compositions comprising MCT, "Schmidl does not teach any form of MCT prodrug.")

In view of such line of arguments Examiner rejects the claim 11 because the metes and bounds of the phrase "medium chain triglyceride prodrug" is not clear and the specification does not adequately set forth the scope of this term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 06-

287138 ("JP ' 138")

The instant claims are directed to methods of treating Alzheimer caused dementia comprising administering to a patient having dementia secondary to Alzheimer and having a diet wherein carbohydrate intake is not restricted an effective amount of MCT.

JP '138 administers MCT to patients suffering from Alzheimer disease. (see abstract, para 0002). JP '138 clearly states that such patients are suffering from senile dementia caused by Alzheimer disease (see para 0002). The patients receiving the composition in JP '138 are not under a carbohydrate intake restriction because their therapy can contain sugar, and various types of mono- or polysaccharides (see para 0023-0024). In fact, JP '138 in para 0034 describes a diet regimen, which contains 54g of cornsarch and 10g of sugar. Thus, the subjects in JP '138 did not have a diet where carbohydrate intake is restricted. Accordingly JP '138 meets all elements of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al US Patent 5,504,072 in view of JP Patent 06-287138.

Schmidl is used to show a normal nutritional compositions comprising carbohydrate and a lipid component comprising medium chain fatty acid triglycerides (MCT) and/or long chain fatty acids. Schmidl does not refer to the use of his composition for treatment of Alzheimer related loss of cognitive function.

JP publication provides application of MCT containing compositions to Alzheimer patients suffering from dementia who are not subject to a carbohydrate-restricted diet. (see abstract and para 0034-0036).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use Schmidl for treating Alzheimer type loss of cognitive function, because Schmidl composition contains MCT, and as taught by JP publication, MCT improves or treats Alzheimer symptoms. Thus, the ordinary skill in the art would have expected that Schmidl composition would also be useful for improving Alzheimer related loss of functional group.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahn timer Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

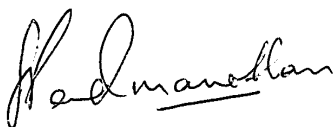
Application/Control Number: 09/845,741
Art Unit: 1617

Page 6

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER